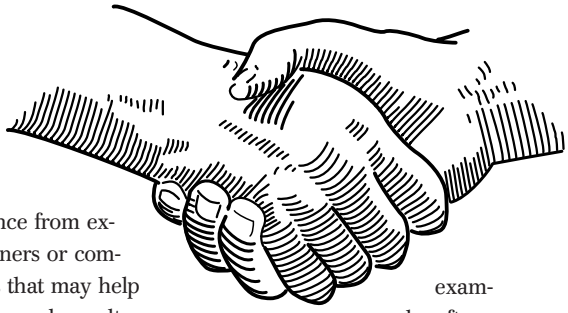
Can Public Health Researchers and Agencies Reconcile the Push From Funding Bodies and the Pull From Communities?

Lawrence W. Green, DrPH, and Shawna L. Mercer, PhD

Responding to growing impatience with the limited application of research findings to health practices and policies, both funding bodies and communities are demanding that research show greater sensitivity to communities' perceptions, needs, and unique circumstances. One way to assure this is to employ participatory research—to engage communities at least in formulating research questions and interpreting and applying research findings and possibly also in selecting methods and analyzing data.

"Community" should be interpreted broadly as all who will be affected by the research results, including lay residents of a local area, practitioners, service agencies, and policymakers. Participatory research should not be required of every project, but when results are to be used for, in, and by communities, those communities should collaborate not only in applying findings but also in determining the ways in which the findings are produced and interpreted. (*Am J Public Health.* 2001; 91:1926–1929)



FOR MANY YEARS, MUCH HAS been made of the need to make better use of research, apply research results more assiduously, disseminate research findings more effectively, and synthesize research into evidence-based guidelines and "best practices" for more immediate application by practitioners. Recently, it has become increasingly clear that there is a need to increase the public's science and health literacy, so that people will consume research more intelligently and school-aged children will be able to integrate scientific methods and facts more fully into their educational experience.[1,2]

Many of these appeals have a patronizing tone to them, which suggests that the researcher is in the best position to decide what practitioners and the public need and then give it to them. The appeal for increased science literacy at least acknowledges a role for the public in the interpretation of science, but even here the assumption is that science will be delivered and consumed. Yet the field of public health yields ample evidence that disseminating the results of studies and telling people how they should incorporate this information into their lives produces minimal behavior change. In contrast, participatory research—research that is generated collaboratively in a partnership between scientists and others—has reemerged in recent decades as an alternative to top-down technical assistance from experts to practitioners or community residents that may help to ensure that research results address real needs and will actually be used.[3]

THE CONVERGENCE OF RESEARCH AND PARTICIPATION

Participatory research has a rich and honored tradition in community development, especially in developing countries, where it has enabled social change and community development projects among populations who were suspicious of the motives of Western researchers.[4] Much of the renaissance of participatory research since the 1960s has taken place in social, educational, and health services development and delivery, some in public health. In health services, nursing has led the way, with collaborative studies between academic nurses and nursing administrators and staff aimed at improving nursing roles and difficult working conditions that have resulted from changes in health care systems.[5]

In public health, the revival of participatory research (also referred to as participatory action research) has been most notable in minority health.[6–8] Native American and Canadian First Nations communities, for example, after decades of serving as subjects for anthropologic and epidemiologic studies, behavioral surveys, and health education program evaluations, have put the brakes on external researchers' exploiting their circumstances while providing very little benefit to their communities. Similarly, African Americans living in inner cities have noticed that their lives have been described publicly by researchers in unflattering—if sympathetic—ways, but they have seen little come of it besides embarrassment and shame.

The recognition by these and other communities that they needed new information about their circumstances that only original research could render converged with a growing recognition by academic and other public health researchers that they could no longer get the data they needed without more active cooperation of the communities. This convergence led to a restriking of the power balance between the observers and the observed. Research subjects became more than research objects. They gave more than informed consent; they gave their knowledge and experience to the formulation of research questions and

methods to be applied in their communities. They became more than the victims described in studies of their health problems and living conditions; they became active partners in identifying key problems and in using the research findings to advocate policies and programs and in program development, monitoring, and evaluation.

WHOSE PARTICIPATION, IN WHAT RESEARCH?

The origins of participatory research sketched above might give the impression that it is a research method designed solely for researcher–public interaction. On the contrary, it is not a research method, nor is it limited to the direct relationship between academic researchers and the public. Participatory research is an approach that entails involving all potential users of the research and other stakeholders in the formulation as well as the application of the research. A wide range of research methods—epidemiologic, experimental, survey, focus-group, qualitative interview—can be applied in the service of participatory research. The choice depends on the methods called for by the research questions and the feasibility of the methods in the particular circumstances.

The issue of whose participation needs to be solicited and incorporated in participatory research hinges on who is to be most directly affected by the research results. Because much of the discussion about participatory research in this issue of the Journal and elsewhere is in the context of community development and community programs, the assumption tends to be that participatory research necessarily engages the lay community. Typically, "community" is understood as a local geopolitical entity, as in the term "community-based participatory research." If, however, the notion of community includes other groupings of people sharing common characteristics or interests, or if the purpose under consideration is something other than community development, there emerge both the need and the opportunity for undertaking participatory research with groups other than community residents.

We therefore urge a broader application of participatory research, one in which participatory research is seen as systematic inquiry, with the collaboration of those affected by the issue being studied, for the purposes of education and taking action or effecting social change.[9] With this more generic definition, "participants" can be public health practitioners and agencies as well as their constituents and clients or community residents.

What are the upper and lower bounds of participation for determining whether research is participatory? Maximum participation occurs when stakeholders remain active partners throughout the study—in the formulation of research questions, selection of methods, and analysis, interpretation, and application of findings. Minimally, stakeholders should be involved at least at the front end of the study, in formulating research questions, and at the back end, in interpreting and applying the findings. This demarcation of the range of participatory research clarifies the distinction between participatory research and basic research, which typically involves only researchers, and action research, which necessarily includes those involved in the action situation (usually practitioners) as subjects of, rather than as participants, in the research. The types of research and various stakeholders are shown in Figure 1.

How does one determine the extent to which participatory research should be incorporated into a given research project? One rule of thumb lies in determining the complexity of the research methods and analyses. Typically, there is no need (and no justification) to drag volunteer participants through a highly technical and labor-intensive research process as long as they have the opportunity to help shape the research questions and interpret the findings. Figure 2 illustrates the varying levels of participation by different actors and stakeholders in different types of research and community development.

CURRENT USES OF PARTICIPATORY RESEARCH AND THE VALUE OF EXTENDING ITS PURVIEW

The happy confluence of mutual interests and action that can be achieved through participatory research remains the exception rather than the rule. Indeed, Congress funded the Prevention Research Centers (PRCs) program of the Centers for Disease Control and Prevention (CDC) to develop innovative ways to con-

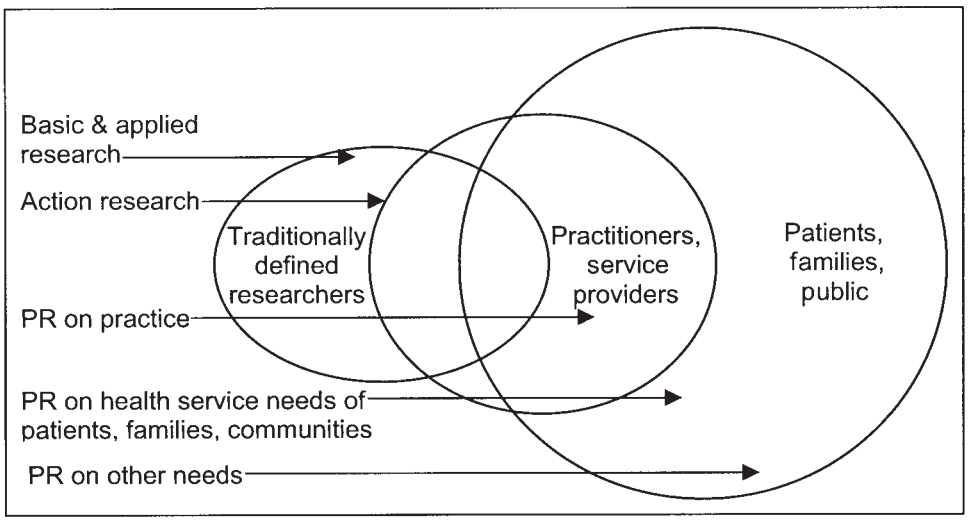
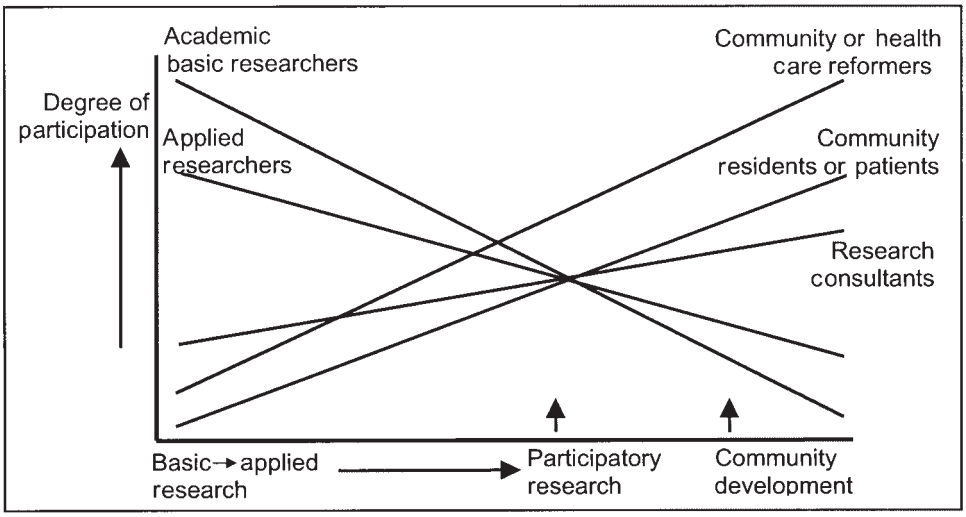


FIGURE 1—Levels of participation and collaboration of different groups in participatory research (PR).



Source. Green et al.[9]

FIGURE 2—Degree of participation by different stakeholders, by type of research or community action.

duct research and demonstration activities that would result in improved public health practice. Yet a 1996 Institute of Medicine panel reviewing the PRCs concluded that the partnership between universities, public health agencies, and communities was falling short of legislative intent.[10]

David McQueen, Patricia Riley, Marshall Kreuter, and Lynda Doll, former national Directors and supervisors of the PRCs program, have led the effort to ensure genuine community input into all 26 PRCs as well as at the national level.[11,12] In this issue of the Journal, Dr. Kenneth Olden, the Director of the National Institute of Environmental Health Sciences (NIEHS) and a strong advocate of participatory research, describes how the NIEHS is responding to this demand.[13] Thus, certain funding bodies are providing the push on academic researchers to engage their subjects more actively; communities are providing the pull.

How can participatory research contribute to better use of science, more assiduous application of research results, more extensive dissemination of research findings, and synthesis of evidence-based guidelines and "best practices" from previous research for more immediate application by practitioners? First, we encourage the expansion of participatory research, both in the number of studies undertaken and in application of a broader definition of participatory research to involve other stakeholders—including practitioners, other service providers, public health departments, and policymakers—in addition to lay community members.

Second, it strikes us that what is most confining about "best practices," and what makes them subject to suspicion from local public health departments, practitioners, and other potential users, is their origins in distant places and under special circumstances. The research that is synthesized into best practices comes from carefully controlled trials conducted in other places—that is, not locally—under the direction and with the resources of "foreign" scientific groups.

Local practitioners and policymakers have every reason to suspect that their circumstances are different from those represented in the studies that went into formulating best practices.[14] Participatory research offers them an opportunity to examine their own circumstances, to pilot-test the best practices within their own context, and to adapt these practices to their own needs. Such local adaptations, in turn, provide valuable feedback to the research community as it seeks to expand the arsenal of evidence-based guidelines and best practices into other areas of public health and as it seeks to explore, account for, and overcome disappointingly low levels of behavior change among lay individuals, practitioners, organizations, and populations.

Public health agencies can provide a bridge between university-based researchers and community-based projects, using participatory research at the agency level to adapt best practices and at the community level to ensure relevance of the research to the community's needs and actions. Engaging communities and practitioners will not invariably improve the internal validity of research, but almost certainly will improve its external validity—that is, its applicability and usability in the settings in which the research occurs. ■

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This commentary was accepted September 18, 2001.

Note. *The views expressed in this commentary do not necessarily represent the views or policy of the CDC.*

Contributors

Both authors contributed to the conception, writing, and editing of this paper.

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What Is Community? An Evidence-Based Definition for Participatory Public Health

Kathleen M. MacQueen, PhD, MPH, Eleanor McLellan, MA, David S. Metzger, PhD, Susan Kegeles, PhD, Ronald P. Strauss, PhD, Roseanne Scotti, MA, Lynn Blanchard, PhD, and Robert T. Trotter II, PhD

Increased emphasis on community collaboration indicates the need for consensus regarding the definition of community within public health. This study examined whether members of diverse US communities described community in similar ways.

To identify strategies to support community collaboration in HIV vaccine trials, qualitative interviews were conducted with 25 African Americans in Durham, NC; 26 gay men in San Francisco, Calif; 25 injection drug users in Philadelphia, Pa; and 42 HIV vaccine researchers across the United States. Verbatim responses to the question "What does the word community mean to you?" were analyzed. Cluster analysis was used to identify similarities in the way community was described.

A common definition of community emerged as *a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings*. The participants differed in the emphasis they placed on particular elements of the definition. Community was defined similarly but experienced differently by people with diverse backgrounds. These results parallel similar social science findings and confirm the viability of a common definition for participatory public health. (*Am J Public Health.* 2001;91:1929–1938)

PUBLIC HEALTH PROGRAMS and policy are often defined at regional and national levels, but community is, literally, where prevention and intervention take place. Community context has been identified as an important determinant of health outcomes.[1] Recognition of these facts has led to increased calls for community collaboration as an important strategy for successful public health research and programs.[2–9] Reviews of the effectiveness of collaborations for improving community health indicate that they can be effective[9–11] but that there are many potential obstacles to realizing the benefits of a participatory approach in both public health research and programs.[8,11–15] In particular, the lack of an accepted definition of community can result in different collaborators forming contradictory or incompatible assumptions about community and can undermine our ability to evaluate the contribution of community collaborations to achievement of public health objectives.[9,16] We are more likely to validate the effectiveness, or ineffectiveness, of collaborative models if we can identify core dimensions of community that have external validity across communities, are consistent with measures that have internal validity within diverse communities, and have predictive value for community-level health outcomes.

Efforts to develop and test HIV vaccines have highlighted social challenges that make community support, trust, and involvement critical for the long-term success of preventive HIV vaccines.[17] Project LinCS (Linking Communities and Scientists) was undertaken to identify effective strategies for meeting these challenges. HIV vaccine efficacy trials and, ultimately, immunization programs require national coordination across diverse communities. The primary Project LinCS research objective centered on identifying ways to make efforts such as large-scale efficacy trials and immunization programs as participatory as possible. A related objective was to demonstrate the value added to research when community members actively participate in the design, implementation, and interpretation of the research.

For this commentary, we analyzed data from 1 component of Project LinCS that asked people how they defined community. The interviews were conducted with diverse groups, thus allowing us to look at the potential effect of local and historic experience on the way people defined community and to determine

whether a single definition of community could effectively encompass the diversity of local experience.

METHODS

Data Collection

Project LinCS participants included African Americans in Durham, NC; gay men in San Francisco, Calif; injection drug users (IDUs) in Philadelphia, Pa; and HIV vaccine researchers in locations across the United States. The 3 local research communities were selected through a competitive funding process. Through a study design collaboratively developed by researchers and local community advisory boards convened for the project, a total of 76 face-to-face, in-depth, open-ended interviews were conducted in Philadelphia, Durham, and San Francisco to identify broad issues, including how people defined community. The interviews were conducted between December 1995 and May 1996. Another 42 in-depth interviews were conducted between September 1997 and September 1998 via telephone with HIV vaccine researchers across the United States; these interviews included a parallel question on defining community. Study protocols and interview guides were approved by local and Centers for Disease Control and Prevention institutional review boards; written informed consent was obtained from all participants (the vaccine researchers mailed back signed consent forms before their interviews).

Interviews were tape-recorded, transcribed into computer text files, and coded by interview question. Verbatim responses to the following question were then extracted for analysis: "The word 'community' means different things to different people. What does the word community mean to you? What is a community?"

Data Analysis

The analysis team developed a structured codebook through a standardized iterative process.[18] The extracted text was read and, on the basis of the text content, a set of initial codes and definitions was proposed. None of the codes were specified before the text was read. Two people then independently coded randomly selected text segments from each participant group and compared results. Coding discrepancies were discussed with the analysis team and the codebook was revised accordingly. This process was repeated until the coders reached a satisfactory level of agreement.

To minimize the possibility that relevant text was missed, all text was double-coded. Intercoder agreement for text associated with each participant group was then assessed for each code by κ scores.[19] For each code with a κ of less than 0.8, discrepancies in coding were reviewed by this commentary's first author, who then decided whether to apply the code to the text in question. For codes with a κ of 0.8 or greater, discrepancies were reviewed by the 2 coders, who then decided which code applications to retain. Text coding and intercoder agreement assessments were done with a developmental version of the software program AnSWR.[20]

For each participant, numeric listings summarized whether or not each code was applied to that person's text. Numeric matrices were then generated to summarize which codes occurred together in the text of all persons within each participant group. From the matrices, complete-link Johnson's hierarchical clusters were generated in ANTHROPAC[21] to identify core elements used to define community. The cluster analysis helped identify similarities in the way people defined community and the extent to which those similarities cut across participant groups.

RESULTS

The 4 participant groups varied in terms of a number of sociodemographic characteristics beyond those immediately reflective of the intentional targeted sampling. Participants who were scientists or from San Francisco tended to have higher levels of education and higher incomes than participants in Philadelphia and Durham. None of the scientists and only 1 of the Philadelphia participants lacked health insurance, although they differed in terms of the primary source of insurance (employer based for scientists and government based for IDUs). Approximately one third of San Francisco and Durham participants lacked health insurance. The mean number of years lived in the current neighborhood of residence was longest for IDUs in Philadelphia (16.5 years), followed by scientists (7.2), African Americans in Durham (5.7), and gay men in San Francisco (2.6).

Of the 118 participants interviewed, 113 provided definitions of community (the question was omitted in interviews with 3 participants in Durham and 2 in San Francisco). Coding identified 17 distinct themes or elements that appeared in the definitions of 2 or more respondents (Table 1). Hierarchical cluster analysis identified 4 clusters among the themes. A core cluster contained 5 elements: locus, sharing, joint action, social ties, and diversity. Each core element reflected some aspect of face-to-face interaction. A second cluster centered on group-based elements of community: divisiveness, leverage, pluralism, and responsibility. These elements reflected social cohesion and community involvement and often acted as boundary-setting or -maintaining mechanisms. Each element of these 2 clusters was cited by at least 4 members of each participant group.

The third and fourth clusters centered on elements that reflected stresses experienced by communities or their members. The first stress cluster included the elements of criminality and drug use. The second centered on the elements of AIDS and unity.

Core Elements of Community

Each of the 5 core elements—locus, sharing, joint action, social ties, and diversity—was cited by 20% or more of respondents (Table 1). Locus was included in 77% and sharing was included in 58% of all definitions. Both locus and sharing were included in 42% of responses, and at least 1 of the 2 was included in 93% of them. Locus and sharing were each cited alone (i.e., without discussion of other core elements) in 16% of responses. Neither joint action nor diversity was discussed alone, and social ties were discussed alone by 2 people (2%). Sharing and locus were discussed by some participants as alternative ways to define community, while others described them as closely interconnected. Definitions that included all 5 elements were elicited by 8 participants (7%); another 13 definitions (11%) included all of the

TABLE 1—Elements Coded From Definitions of Community From All Sources Within Project LinCS (n = 113)

Definitional Element	Brief Definition	No. of Participants Citing Element (%)
Locus	Physical location; place with people	87 (77)
Sharing	Shared perspective; common interests	65 (58)
Action	Joint action or activities	57 (50)
Ties	Social ties, relationships	56 (50)
Diversity	Differences or diversity (e.g., age, race, income, behavior)	27 (24)
Divisiveness	Fragmentation, division into disputing factions	17 (15)
Leverage	Effectiveness; ability to influence resource availability	17 (15)
Responsibility	Importance of accepting consequences of individual action	17 (15)
Pluralism	Coexistence of 2 or more distinct cultural traditions	15 (13)
Criminality	Impact of criminal activities	12 (11)
Unity	Community fellowship	15 (13)
Drug use	Impact of drug use and addiction	11 (10)
Nonexistent	No community; concept holds no meaning	9 (8)
AIDS	Impact of HIV/AIDS	7 (6)
Services	Availability of social services and programs	6 (5)
Religion	Religious or spiritual focus	5 (4)
Survival	Adaptability, resourcefulness	4 (4)
Other elements		10 (9)

core elements except diversity. These 2 combinatorial groups account for 27% of all definitions offered (Table 2). Each of the core elements is described below; the quotations in the box on p 1933 illustrate how these elements were woven into actual responses.

Locus: a sense of place. Locus encompassed the idea of community as something that could be located and described, denoting a sense of place, locale, or boundaries. One can be "in" a community physically whether or not one identified as being a member of the community. People referred to locus in terms of specific areas (neighborhood, corner, block; street, road, highway; zip code area; village, city, county), with reference to specific settings (home, household; workplace; local taproom or bar, corner grocery store, newsstand, sandwich shop, bookstore; community building, swimming pool, recreation center; church, school), and in terms of general locations (an area or place where people live together; environment or surroundings).

Sharing: common interests and perspectives. Sharing referred to the existence of shared perspectives and common interests that contributed to a sense of community. Community members were described as sharing the following:

- Values, norms, mind-set, viewpoint, ideology, beliefs, visions
- Passions, obsessions, interests, likes and dislikes, opinions, concerns
- Activities, goals, objectives
- Symbols, jargon
- Skin color, sexual identity
- Tribulations, oppression, repression, history

Sharing contributed to a sense of community through the following:

- Common issues, threads, beliefs, factors
- Being in tune with each other
- Comfort, familiarity, togetherness, identity, recognition

Joint action: a source of cohesion and identity. Joint action was described as a source of community cohesion and identity. A conscious intent to generate community through action was not viewed as necessary; rather, joint action was seen as leading naturally to the creation of community. Community was described as emerging from the joint actions of people who did the following:

- Socialize, hang out, converse, intermingle, gossip, "shoot the shit"
- Work at the polls, volunteer at the library, run phone banks, train people, work on projects
- Keep people informed about resources, services, and what's happening
- Paint houses; paint the street; push brooms; shovel snow; keep up the area; clean up the block, neighborhood, yard, or house; have block parties
- Give food, share resources, provide for neighbors in need
- Watch over, check up on, look out for, keep an eye on each other
- Set values and goals for the children, have their butts kicked a little bit if they're slacking off, push for the betterment of everyone, do something positive, improve the neighborhood
- Get together, do things together, work together, act together, participate, plan, get things done, get inspired, engage in activities, give input, accomplish goals
- Write, speak, educate, encourage, pray

Social ties: the foundation for community. Social ties were described in terms of interpersonal relationships that formed the foundation for community. In some instances, such relationships were described as requiring little, if any, effort or ongoing acknowledgment on the part of the individual. The types of relationships cited included the following: family, parents, siblings, cousins; roommates, household; lovers, partners; friends, neighbors, associates, coworkers, acquaintances; role models, support groups.

In addition, participants often described characteristics that they associated with community-based relationships or people. Community, participants said, meant ties with people

- Whom they can trust
- With whom they feel comfortable
- Who care about each other

TABLE 2—Co-Occurrence of Core Elements in Definitions of Community From All Sources Within Project LinCS

Co-Occurring Elements	No. of Respondents (%) (n = 113)
All 5 (locus, sharing, joint action, social ties diversity)	8 (7)
Any 4	22 (20)
Diversity, locus, sharing, social ties	2 (2)
Joint action, locus, sharing, social ties	13 (12)
Joint action, diversity, sharing, social ties	3 (3)
Joint action, diversity, locus, social ties	2 (2)
Joint action, diversity, locus, sharing	2 (2)
Any 3	26 (23)
Locus, sharing, social ties	5 (4)
Diversity, sharing, social ties	1 (1)
Diversity, locus, sharing	3 (3)
Joint action, locus, social ties	6 (5)
Joint action, locus, sharing	8 (7)
Joint action, diversity, sharing	1 (1)
Joint action, diversity, locus	2 (2)
Any 2	33 (29)
Sharing, social ties	1 (1)
Locus, social ties	11 (10)
Locus, sharing	6 (5)
Diversity, sharing	3 (3)
Joint action, social ties	2 (2)
Joint action, sharing	3 (3)
Joint action, locus	7 (6)
Only 1	20 (18)
Locus	12 (11)
Sharing	6 (5)
Social ties	2 (2)
No core elements cited	4 (4)

• With whom they interact, hang out, choose to be sociable, spend time, connect
• Who are known to them
• Whom they always see in the background or around them
• With whom they grew up

Diversity: social complexity within communities. Diversity emerged in discussions of social complexity (e.g., communities within communities, stratification, interwoven groups, hidden communities, or multiple levels of community). As used here, diversity excluded culturally based ethnic distinctions (see the discussion of pluralism below). Discussions of diversity focused on a larger societal view of community and made reference to differences in interpersonal interaction that resulted from the following:

• Different levels of interaction between people, from the intimate to the superficial
• Demographic and social diversity in the form of race, ethnic origin, socioeconomic status, sexuality, drug use, profession
• The presence of specialized groups that performed needed tasks, such as activists and service providers
• The presence of groups that identified with overlapping or multiple communities
• The presence of groups that were disowned, stigmatized, stereotyped, or distrusted within communities

As seen in Figure 1A, the saliency of each of these elements for the core definition of community varied by participant group. Action, locus, and social ties were the most consistently discussed elements across all groups. Sharing predominated in interviews among scientists and gay men in San Francisco, while diversity was discussed relatively infrequently by all groups except the San Francisco participants. Thus, the relative saliency of sharing and diversity appears to be an important distinguishing characteristic of communities.

Despite group differences in the saliency, frequency, and co-occurrence of the 5 core elements, the overall response pattern indicates that these 5 elements were universally recognized within each community as a whole, if not by every community member. In anthropologic terms, the elements constitute a common cultural domain.[22,23] Together, they suggest a full definition of community as a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographic locations or settings.

Group-Based Elements of Community

Like the core elements, the group-based elements of community—divisiveness, leverage, pluralism, and responsibility—had meaning across all of the participant groups but were less frequently cited than the core elements (Figure 1B). Overall, at least 1 of the group-based elements was cited by 36 (32%) of the participants, including 18 (75%) of the participants from San Francisco, 8 (32%) from Philadelphia, 4 (18%) from Durham, and 6 (14%) of the scientist participants. Nineteen participants cited 2 or more group-based elements. Discussions centered on the implications of individual-level behavior for the community as a whole and on the relationship of the community to larger society (see box p 1934).

Divisiveness referred to descriptions of community fragmentation or a lack of unity, often expressed as an overemphasis on individualism and self-interest, or as attitudes that hindered unity and cooperation. Divisiveness was often discussed in the context of the need for or a perceived lack of responsibility on the part of community members.

Discussions of *leverage* centered on the potential ways that groups or individuals can bring about positive or negative consequences for the community as a whole. *Pluralism* referred to discussions of the maintenance of distinctions between coexisting ethnic groups. Unlike the core element of diversity, which focused on variability in a wide range of individual-level characteristics, pluralism implied ethnic and cultural distinctions among people living in the same area. Cultural pluralism is an anthropologic concept defined as "social and political interaction within the same society of people with different ways of living and thinking."[24(p658)] The challenges of living in a pluralistic commu-

Core Elements of Community

DURHAM AFRICAN AMERICAN: I think community can be defined in 2 different ways. There's a community that you define as such because you are forced by where you live, by your upbringing to be around those people. This isn't a voluntary type of thing. This is your community because you live there. The place you call your hometown is your community because you grew up there, you knew people there. You didn't really have a choice as to whether that would be your community or not, it just was. And so you were molded and informed by that surrounding, by that society, but it wasn't a voluntary type. And that's how I would describe my work community. It is my community because I have to work there and it is my workplace. That's not to say that I don't choose at times to include these people in other aspects of my life. But certainly, the people I choose to be sociable with most aren't people I share the same job with.

SCIENTIST: A community is a fairly broad term in my mind that encompasses groups of people working together toward the same goal. . . . I would say I identify with the HIV research community, the HIV care community, my own personal community with my family, certainly my regional community.
INTERVIEWER: Okay, when you say family community, is that just your immediate family?
SCIENTIST: I mean school communities related to my children's schooling, and the communities here in [place name] that are involved in providing support, such as the [AIDS foundation name]. And that's what I mean by community. . . . I mean, there's my neighborhood. That's what I mean by geographical locale. Political community, I suppose I would say that as a Democrat I'm a participant in the political groups here in town and nationally. . . . I think that our communities are less dependent these days on actual physical adjacency, if you will, that the Internet has brought many people together, and when I say I'm part of the AIDS research community, I think of that as a worldwide community.

SAN FRANCISCO GAY MAN: I lived alone for a while after [my partner] died and I really hated it. I really felt very lonely and now I live in a situation with a good friend. . . . There's a sense of comfort in that. Because, you know, he's single and I'm single and we have a group of friends and there's a lot of connection, that we kind of create community. I think we as gay and lesbian people create family too in a lot of ways that are not biological and I think [in] some ways that sense of creating family is creating community, that's what we support ourselves and surround ourselves with.

PHILADELPHIA IDU: Well, in the drug culture, I wouldn't call that a community, you know. I would just call that a part of the community that's just tryin' to survive but [what] community means to me is a way people look out for one another and they do things together, insofar as socializing together, praying together. You know, they have a mutual bond but see, you know, and some of that goes on in the community, you know, and that drug culture can be right here but you still have a group of people that tries to keep the neighborhood together and try to set the right values for the children.

nity were described primarily by African American, Latino, and Asian/Pacific Islander gay men in San Francisco who attempted to navigate simultaneously among problems related to their ethnicity (e.g., racism, restrictive immigration laws) and those related to their sexual identity (e.g., homophobia, rejection by family members).

Responsibility was discussed in terms of the way people were or should be responsible for their own behavior, including how their behavior reflected on or affected the community as a whole. As such, leverage and responsibility were often discussed together.

The Impact of Stress on a Community

Two clusters emerged that centered on stresses affecting community. The first centered on the negative effects of *criminality* and *drug use*. As seen in Figure 1C, although these were more frequently discussed by participants in Durham and Philadelphia, they were described as elements that undermine community in San Francisco as well. In contrast to the stresses of drug use and criminality, *AIDS* was more likely to be described as something that brought people together in a common struggle, increasing a sense of *unity*. For one Durham participant, the violent death of a child prompted a similar response, motivating her to work to improve circumstances in her community (see box p 1935).

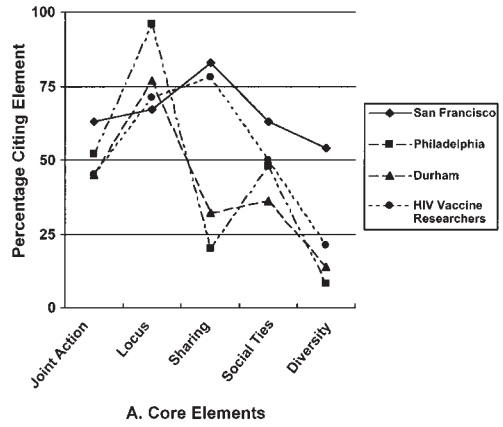
Statements that community was *nonexistent* were made by 6 respondents from Philadelphia and 3 from San Francisco. These discussions often included statements about diversity or pluralism as an obstacle to the development of community, by contributing to a lack of common identity or undermining a sense of responsibility to the group. For the Philadelphia drug users, the lack of community was sometimes seen as pervasive, or the drug culture was viewed as a noncommunity that was both separate from and surrounded by a functional local community that included the elements of locus, action, ties, and sharing.

DISCUSSION

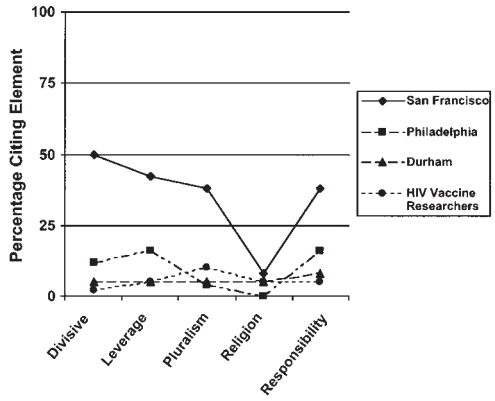
The Elements of Community

Collectively, the Project LinCS participants described community by using a limited set of elements that reflect concepts previously noted in the social science literature. Four of the core community elements identified here through empiric means—locus, sharing, joint action, and social ties—are commonly found in social science definitions of community. In an early literature review of 94 definitions, Hillery[25] found that two thirds cited social interaction, geographic area, and common ties as essential elements of community life, and almost three fourths cited area and social interaction. A review of an additional 60 definitions subsequently published in the social science literature found little change beyond a slight increase in emphasis on "people with common ties residing in a common geographic area."[26]

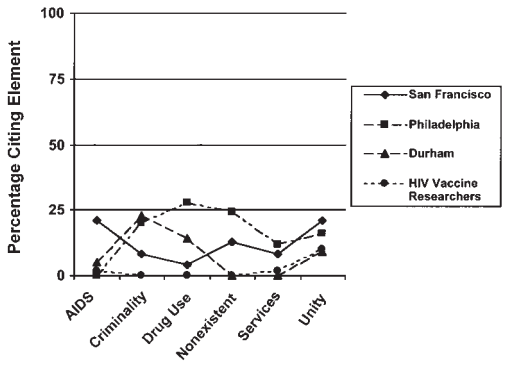
Taking a different approach, McKeown and colleagues[27] analyzed the way community was conceptualized in 4 classic ethnographic studies conducted by 2 anthropologists at different stages in their careers. They noted overall agreement in the use of 4 basic attributes to describe community: locality, biological and social membership, common institutions, and shared actions. From a psychological perspective and using an empiric approach that parallels our own, Chavis and colleagues[28] identified 4 elements composing a sense of



A. Core Elements



B. Group-Based Elements



C. Stress Elements

Note. San Francisco = gay men in San Francisco, Calif; Philadelphia = injection drug users in Philadelphia, Pa; Durham = African Americans in Durham, NC; HIV vaccine researchers = HIV vaccine researchers across the United States.

FIGURE 1—Saliency of definitional elements of community by participant group: (A) core elements; (B) group-based elements; (C) stress elements.

Group-Based Elements of Community

Divisiveness and Responsibility:

DURHAM AFRICAN AMERICAN: Now it's, like, everybody is on their own. Nobody cares about what happens, and you don't even have people participating in community-based projects.

PHILADELPHIA IDU: You got somebody over here with a big car, plenty money, and the kids see this. They're influenced by this, but by the same token, there's his grandmother, his mother, his aunt trying to say, "Well, no, that's not the way, come on, we goin' to church, or we goin' to the Center," you know.

Leverage and Responsibility:

SAN FRANCISCO GAY MAN: Things are gonna start to grow, and if you wanted those little businesses to survive, why weren't you giving them your business? Why weren't you going to lunch at their place? Why weren't you buying books at their store? Oh, you weren't? But yet . . . you want to choose who comes in there? I said that's not life, that's not business.

PHILADELPHIA IDU: It was like community because people were concerned. I can go down the street and break out somebody's window playin' baseball, right, and before I got home, my mother would know about it and everybody that was involved. You know. It's because everybody was concerned about what was going on in the neighborhood. Just like, on the same note, if we didn't have any food, you know, and somebody would get word of it, friends would bring us food over.

Pluralism:

PHILADELPHIA IDU: When I was growin' up there it was a White neighborhood, now it's all Spanish and all Black and all everything, Chinese, and Koreans and so it's kind of not a community anymore, it's so mixed up that there's no nothing there anymore. Koreans messin' with Koreans, Whites messin' with Whites, Blacks messin' with Blacks and it's all mixed up there and nobody bothers nobody no more.

community: membership, influence, integration and fulfillment of needs, and shared emotional connection.

Using data from a study in a suburb of Toronto, Wellman and Wortley[29] argued that locus was of decreasing importance for urban communities and that these were best described in terms of "personal community networks" that are socially diverse in composition, spatially dispersed, and sparsely knit. Others have suggested that the decreasing importance of locus actually leads to a sense of the loss of community. For example, Glynn[30] evaluated the relationship between people's ideal sense of community and their perception of their actual community in 3 diverse settings (an Israeli kibbutz and 2 dissimilar cities in Maryland) and found that neighborhood identification was important for the development of an actual sense of community.

Patrick and Wickizer[9] reviewed social science definitions of community with an eye toward developing and implementing effective community-level health interventions. They identified 3 broad conceptual approaches to the definition of community: those that defined community as *place*, as *social interaction,* and as *social and political responsibility.* The concept of social and political responsibility is similar to our core element of joint action, combined with our group-based elements. Patrick and Wickizer[9(p51)] offered a work-

Impact of Stress on a Community

PHILADELPHIA IDU: Do you know how many people was tryin' to rob me outta that coat right there? [Points to her coat on hanger.] I mean, these are people that's in the community, okay, and that this is supposed to be a community—why is everybody doin' what they doin' to one another?

SAN FRANCISCO GAY MAN: Crystal meth has really bothered me, just 'cause I see it as really damaging to my community. . . . I see people whose lives are getting all messed up, and I see that it's everywhere. I mean, it's almost epidemic in the gay community.

DURHAM AFRICAN AMERICAN: I never mingled or associated with anyone. I didn't want to be a part, you know, but I think the thing that really brought me out was when the [child] got killed over here. . . . The child was sittin' out on the stoop, other people were sittin' out on their stoop and stuff, and it was someone shootin' at another person, and one of the shots hit the child and she got killed over here in our neighborhood, and I think that is what basically brought me out to want to be a part of the community and get something done about what's goin' on over here.

SAN FRANCISCO GAY MAN: . . . as I get older, I have a stronger sense of [community], or a stronger sense of commitment to the community. I mean, you know, that's why I'm getting increasingly involved with AIDS activities.

SAN FRANCISCO GAY MAN: I don't think we have much of a gay community, unfortunately. I wish we did. But we don't because of what we are. We're everything. We're Black and we're White and we're poor and we're rich, so how can we have a gay community—I think that's a really silly word, the "gay community," because it doesn't really exist. That's like the White, male, heterosexual community. I think that's silly.

PHILADELPHIA IDU: You ask me what the community is. Nothin', zilch. To me there is no damn community.

ing definition of community as "the entire complex of social relationships in a given locale, and their dynamic interaction and evolution in working toward [the] solution of health problems."

The importance of local diversity has not been previously articulated in definitions of community, although the effect of such diversity on health measures has been noted. For example, Sampson and colleagues[31] pointed to the need to explore the meaning and sources of variation within neighborhoods or local communities for collective efficacy for children. Zakus and Lysack[16] noted that communities are rarely, if ever, a homogeneous whole and that this represents a major challenge for successful community participation in setting health policy. The fact that diversity emerged as a core element in our empiric exploration of definitions of community was driven to a great extent by the experiences of the gay men who were interviewed. San Francisco is a national and international meeting ground for gay men. The interviews we conducted suggest that many of them are consciously seeking to build a community based on a positive valuing of unity, diversity, and cultural pluralism. With increased mobility and immigration throughout the United States, the importance of diversity for community structure and function is likely to increase in other locations and for other populations. The challenges presented by local diversity, in turn, are likely to become increasingly important for public health efforts as well.

Implications of the Experience of Community for Collaboration

The saliency of the different elements of community for each of our 4 participant groups had implications for the ways in which our collaborations developed. For gay men in San Francisco, a strong sense of shared history and perspective was a dominant theme, followed by a sense of identity with a specific location, the creation of strong and lasting social ties, established avenues for joint action, and the role of diversity. This profile is superficially similar to the one elicited from the vaccine researchers; however, particular elements were discussed less frequently than in San Francisco. Significant differences also existed with regard to how the elements were discussed. Most of the San Francisco participants had thought about community, and many were struggling to reconcile their need for community with a sense of marginalization from society at large. In contrast, the scientists tended to describe themselves as well grounded in multiple communities.

The profiles for Durham and Philadelphia also had a surface resemblance to each other. In contrast with San Francisco participants and the scientists, Durham and Philadelphia participants viewed locus as the principal element of community. This was especially true for IDUs in Philadelphia. Both groups emphasized the importance of joint action and social ties, while minimally discussing the role of diversity. African American participants in Durham included more college-educated and nonheterosexual individuals than did Philadelphia participants and, perhaps as a result, were somewhat more likely to discuss the role of shared perspectives for community than were Philadelphia participants. In both Durham and Philadelphia, most people described community as a "given" in their immediate environment. However, for IDUs, the given community environment was less likely to be described as supportive than for African Americans in Durham.

These differences in the way people perceived and talked about the core elements of community suggest the need for *multiple models of collaboration for public health research and programs.* In fact, the collaborations we established in San Francisco, Durham, and Philadelphia illustrate this need. At each site, researchers worked with a community advisory board (CAB), but in different ways.

The San Francisco collaboration. In San Francisco, community advocates and activists were collaborating with HIV vaccine researchers before Project LinCS was funded. Consistent with the emphasis on sharing seen in Figure 1A, the CAB members placed a high value on opportunities for in-depth discussion with both local and nonlocal Project LinCS collaborators. Similarly, they recognized the importance of existing social ties and activities and were careful not to allow Project LinCS to draw energy away from other HIV vaccine work. As a result of their long involvement in treatment and prevention activities,

many San Francisco CAB members had a sophisticated understanding of research. Reflecting the saliency of joint action for the community, the CAB used this knowledge to take an active role in developing the protocol and interview guide for the scientists. Additionally, half of the scientist interviews were conducted by a San Francisco CAB member (with full support from the Philadelphia and Durham CABs). The CAB also collaborated with local investigators in the development of a complex targeted sampling plan to ensure maximal diversity of Project LinCS participants, reflecting their awareness of the important role of diversity and pluralism in their community.

The Durham collaboration. In Durham, the African American community was beginning to mobilize around AIDS when Project LinCS began. Here, the local investigators had to reach out widely to people and organizations with links to the African American community. A socioeconomically diverse group of representatives came together and volunteered to work with the researchers, meeting at a historically African American university campus in Durham. Consistent with our analysis that showed an emphasis in Durham on locus and joint action, the CAB focused its efforts on making sure that the project provided tangible benefits to the local community. These efforts resulted in a brochure on questions to ask when volunteers were invited to participate in research and a local newspaper insert on lessons learned from the project, which was distributed to more than 11 000 houses in predominantly African American neighborhoods.

The Philadelphia collaboration. The Philadelphia investigators had a long-standing relationship with IDUs that centered on a storefront research program. About a year before Project LinCS began, the investigators invited study participants to form a CAB. The meetings were initially chaired by the principal investigator, but later the CAB members established their own set of rules and took on increasing responsibility for the functioning of the board. Philadelphia LinCS participants emphasized locus, action, and social ties in their definitions of community. Similarly, the CAB defined its primary role as one of maintaining and building linkages between the research staff and the IDUs in the surrounding neighborhoods, a community that functioned largely through informal structures and at the margins of society.

The Role of Community Representation for Collaboration

Israel and colleagues[13] and Zakus and Lysack[16] noted that participatory approaches such as ours that rely on representation can lead to conflicts with regard to how community is defined and who may legitimately represent the community. Our experiences, and our empiric data, suggest that an important element for success may be ensuring that CAB representatives are actively connected to diverse people in their local communities and empowered to function in ways that are meaningful to their community base. Other research supports this view. Conway and colleagues[32] compared perceptions of health priorities among local District Health Council members and among a random sample of household residents in Chicago and Cook County, Illinois. The results showed substantial agreement in priorities, indicating that advisory boards can effectively represent community perspectives regarding health priorities. Jewkes and Murcott[33] presented results of a qualitative assessment of the uses, meanings, and interpretations of community participation in the context of the World Health Organization's Healthy Cities Project as implemented in the United Kingdom. In interviews with 50 participants drawn from health, local government, and voluntary sectors, they found that "being known" was the most fundamental requirement of an effective representative. Data from a case study by Bond and Keys[34(p37)] support the feasibility of empowering multiple community groups simultaneously through a single advisory board "when the board culture promoted inclusionary group processes and the activation of member resources."

If collaboration is to be an effective component of public health research and programs, it will require a greater understanding of the way people interact individually and as groups. The definition of community provided in this commentary supplies a potential framework for investigating such interactions. Each of the core elements composing community (locus, sharing, joint action, social ties, and diversity) can be evaluated relative to public health outcomes through existing social science models, including social network analysis,[35–37] sense of community,[38–42] social capital,[43,44] cultural domain analysis,[22,23,45,46] and geographic information systems.[47] Such models provide a solid foundation for a systematic approach to community-level and community-based public health research and programs.

CONCLUSIONS

The results of our analysis point to a core definition of community as *a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings.* Our results further suggest that a cookbook approach to participatory programs and research will not work because the experience of community differs from one setting to another. Rather, each research collaboration, and each level of collaboration from the local to the national and the international, must reconcile the differences and similarities among the participating communities.

Community collaboration in public health programs and research presents many challenges, in part because community has been defined in ambiguous and contradictory ways. Despite important differences in the experience of community, our study suggests that people largely agree about what community is. The empiric evidence, in turn, is bolstered by established social science theory. Additionally, existing social science tools provide a strong foundation for measuring and evaluating the contributions of community collaboration to the achievement of public health objectives.

Thus, a sound empiric and theoretic basis exists for achieving consensus on a definition of community for public health. Consensus will facilitate the systematic comparison of local populations by directing attention to a set of core elements for mea-

surement. Systematic comparison, in turn, will facilitate hypothesis testing and strengthen the scientific study of the role of community in public health. For example, it could help us identify functional thresholds for the core elements, such that groups above the threshold are significantly more likely to experience beneficial health outcomes than those below the threshold. In other words, it can help us understand how to build and support "good" communities that enhance the health of their members. It can help us understand which characteristics or combinations of characteristics are necessary or sufficient for supporting intermediate goals such as the sustainability of prevention programs or the diffusion of beneficial health practices. And it can provide a sound theoretic basis for building successful community collaborations in public health through the systematic evaluation of who participates, why they participate, what they share, what they do, and how participants are connected to each other and to their constituencies. ■

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This commentary was accepted June 29, 2001.

Contributors

K.M. MacQueen contributed to the conception, analysis, and interpretation of data and was the principal author. E. McLellan contributed to analysis, interpretation, and authorship. D.S. Metzger, S. Kegeles, R.P. Strauss, and L. Blanchard contributed to the conception, acquisition of data, and critical revision. R. Scotti contributed to analysis, interpretation, and acquisition of data. R.T. Trotter II contributed to the conception, analysis, interpretation, and critical revision.

Acknowledgments

This research was supported by Centers for Disease Control and Prevention cooperative agreements U48/CCU409660 (University of North Carolina at Chapel Hill), U64/CCU910851 (University of California at San Francisco), and U64/CCU310867 (University of Pennsylvania).

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The Role of Community Advisory Boards: Involving Communities in the Informed Consent Process

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Ethical research involving human subjects mandates that individual informed consent be obtained from research participants or from surrogates when participants are not able to consent for themselves. The existing requirements for informed consent assume that all study participants have personal autonomy; fully comprehend the purpose, risks, and benefits of the research; and volunteer for projects that disclose all relevant information. Yet contemporary examples of lapses in the individual informed consent process have been reported.

The authors propose the use of community advisory boards, which can facilitate research by providing advice about the informed consent process and the design and implementation of research protocols. These activities could help reduce the number of individual informed consent lapses, benefiting study participants and the scientific integrity of the research in question. (*Am J Public Health.* 2001;91: 1938–1943)

INDIVIDUAL INFORMED consent has traditionally been understood as a substantive ethical requirement, an agreement between the researcher and the research subject concerning the roles and obligations of each party in a study. The researcher seeks to enroll fully informed, consenting, individual subjects in a study. When informed consent is not obtained, or when subjects are not fully informed, research abuses can occur. Community activists, joined by some scientists, have publicized the limitations of individual informed consent and have argued for the incorporation of community perspectives or "voices" during informed consent and throughout the research process.[1–4] Community involvement has been part of international research in developing countries for some time. Issues of culture and individual autonomy, however, must be dealt with to create partnerships between researchers, study participants, and communities that will protect participants.

Here we review examples of situations in which the required process of individual informed consent failed to ensure that study participants were fully aware of the implications of their involvement. In response to this problem, we propose that individual informed consent be augmented by community advisory boards (CABs), which can facilitate research by advising about the informed consent process and the design and implementation of a study.

BACKGROUND ON INDIVIDUAL INFORMED CONSENT

Since the Nuremberg Code of 1947,[5] several organizations have worked to provide a set of ethical guidelines for the conduct of research involving human subjects; these guidelines include specific references to obtaining informed consent. The Council for International Organizations of Medical Sciences and the World Medical Association, which focus on international research, and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which focuses on research conducted nationally, are responsible for setting and amending the guidelines that govern research on human subjects.

The Council for International Organizations of Medical Sciences has formulated 15 guidelines, 9 of which, in its most recent document, address issues of informed consent. These issues include those that may occur in vulnerable populations (e.g., women, the mentally challenged, minors) where individual informed consent would be difficult, if not impossible, to achieve.[6] The World Medical Association has recently

amended the Declaration of Helsinki, positing 7 principles for obtaining informed consent that not only address consent involving vulnerable populations but also include practical guidance on obtaining consent in situations where medical research is combined with medical care.[7]

Finally, the Belmont Report,[8] developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, establishes 3 fundamental ethical principles that are relevant to informed consent—*respect for persons*, *beneficence*, and *justice*. These principles require that sufficient information about the study in question (e.g., risks and benefits) be disclosed to study subjects, that the information be conveyed to subjects in an easily comprehensible manner, and that subjects endorse statements indicating that their participation is voluntary—that is, free of coercion and undue influence. Researchers have an ethical and legal obligation to ensure that these 3 elements of informed consent are honored when individuals agree to participate in research.[9]

RESEARCH LAPSES RELATING TO INDIVIDUAL INFORMED CONSENT

Although informed consent requirements were established specifically for the purpose of providing protection for human subjects, these requirements are insufficient. Recent examples exist, in both industrial and developing countries, in which informed consent has failed to ensure that participants recognized that their participation was voluntary, understood the research in question (including study terminology and all potential benefits and risks), and were sufficiently informed to make an educated decision regarding their participation.

The examples listed in Table 1 illustrate that the requirements of informed consent—voluntariness, full disclosure, and comprehension—do not always protect or sufficiently inform human research subjects.[11–27] Furthermore, over 90% of the cases in which research abuses have taken place are associated with lapses in informed consent.[28] Indeed, in 2 studies where research abuses were reported,[19,21] the federal Office for Protection From Research Risks (now the Office of Human Research Protections) of the US Department of Health and Human Services cited the manner in which research subjects or parents of research subjects were informed about the studies. Given that the target populations in these studies were vulnerable (children and poor, HIV-seropositive Haitians), greater efforts are necessary to ensure that the rights of all human subjects are protected. We believe that protecting and fully informing human research subjects requires supplementing the current methods of obtaining informed consent with increased involvement and advocacy at the community level.

TABLE 1—Examples of Research Lapses Relating to Individual Informed Consent

Lapse	Explanation	Examples
Lack of voluntariness	Potential coercion to influence participation has occurred	Conflict of interest: Investigator is the subject's physician[10] Subjects are asked to participate when under considerable duress[11–13] Subjects are asked to participate when they have few or no options (e.g., placebo-controlled surgical trials)[14–16]
Incomplete disclosure	Subjects are misinformed or not fully informed about the intent of the research in question, potential risks associated with the research, or previous pertinent research	In a multisite breast cancer prevention trial of the drug tamoxifen, pertinent information about side effects was omitted or minimized in consent forms[17–18] In a New York study, parents were not informed that their children with attention deficit–hyperactivity disorder were taken off their medication and subjected to brain chemistry tests [19] In a study of serodiscordant couples in Haiti, subjects were not told that the purpose of the study was to observe couples in which 1 partner was HIV-seropositive[20–21] In a zidovudine (AZT) trial in Cote d'Ivoire, 1 female subject was not told that the experimental treatment had been proven to reduce vertical transmission of HIV in a US trial[13,22–23] In a trial of isoniazid (INH) for tuberculosis in Uganda, HIV-positive subjects were not told that INH is routinely used in the United States to prevent tuberculosis[24–25] In a study conducted in Los Angeles, researchers did not properly inform parents providing consent for their children about previously reported adverse side effects of an investigational measles vaccine[26–27]
Confusion about study terminology	Subjects do not fully understand the scientific terminology or the study's purpose as presented to them	Parents of critically ill babies were confused about the words *random* and *placebo*; they perceived random assignment to mean either acceptance or rejection of their babies as subjects in a UK study[11] One female subject in an AZT trial in Cote d'Ivoire perceived that participating would help her child and ease her childbirth[13] HIV-positive subjects in a trial of INH for tuberculosis in Uganda were told that they would be assigned to one of the treatment groups, with one of the groups being "treatment with a placebo drug"[24–25] Subjects may not have understood that placebo-controlled surgical trials in the United States were risk-free[14–16]

PROMOTING EFFECTIVE INDIVIDUAL INFORMED CONSENT

A Proposal to Implement Greater CAB Involvement

The lapses of the individual informed consent process demonstrate that participants may not be autonomous in their ability to make decisions about research participation and that researchers may not always respect the interests of human subjects while pursuing the goals of research. Traditionally, informed consent focuses on the relationship between the researcher and the participant. Using the principles of community consultation and participatory research,[4,29] we recommend enhancing this process by developing a partnership between researchers and the community.

A CAB is composed of community members who share a common identity, history, symbols and language, and culture.[30] For example, gay activists and gay HIV-affected individuals could serve on a CAB for an AIDS clinical trials group interested in recruiting participants from the gay community. Representatives from the African American community (e.g., young women, faith leaders) could serve on a CAB that is linked to a community-based study testing a comprehensive prenatal program for high-risk minority pregnant women.

Using CABs to facilitate the informed consent process fundamentally changes how researchers relate to participants. Table 2 illustrates how this might work; the elements of informed consent developed by Beauchamp and Childress[31] are used as the basis for defining the functions and responsibilities of the study participants, the CAB, and the investigators. It is assumed that participants have a high degree of personal autonomy and therefore fulfill their functions and responsibilities for each of the informed consent elements listed. Similarly, investigators are expected to fulfill their roles in protecting and fully informing participants by adhering to their functions and responsibilities.

The CAB, since its members come from the same community as the participants, serves as a liaison between participants and researchers. In this role, the CAB can help in the development of

TABLE 2—Functions of Study Participants, Community Advisory Boards, and Investigators in the Research Process

Elements	Functions and Responsibilities		
	Participant	Community Advisory Board	Investigators
Threshold elements			
Competence—The capacity to understand and reasonably decide about participants' rights and the process of research participation	Is legally competent to decide about research participation	Is competent to sponsor research and to act in an accountable manner to represent community perceptions of research	Are obligated to maximize participants' ability to make decisions; are obligated to follow ethical guidelines of informed consent; are scientifically competent to produce and disseminate valid research findings
Voluntariness—The exercise of free choice in making a decision about research participation; the absence of coercion in research participation	Exercises individual free choice in deciding about research participation	Expresses the community's desire to participate in research; conveys to participants their right to refuse	Are obligated to construct a situation that ensures voluntary participation
Informational elements			
Disclosure—The process of making known relevant risks, benefits, conflicts of interests, and research issues to those directly or indirectly affected or involved in research	Is honest when enrolling in research by revealing information needed by researchers	Elicits from researchers information that the community needs to have; disseminates necessary information to participants, researchers, and community members	Are obligated to fully reveal relevant information and ramifications of research to institutional review board, community advisory board, and participants
Understanding—The ability to evaluate information and recommendations	Is able to evaluate whether to give consent for a specific research study	Evaluates and communicates risks and benefits of research	Anticipate and provide information needed by communities and participants to evaluate research
Consent elements			
Decision to act—The process of agreeing or disagreeing with a research plan	Determines whether to give consent for enrollment in a specific research study	Formulates recommendations to potential participants, community members, and researchers; includes decision to proceed with and monitor or to withdraw support from a specific research study	Are able to accommodate to community and individual concerns about the design or conduct of a specific research study
Authorization—Legal sanctioning of participation in a chosen research plan	Legally and formally agrees to enroll in a specific research study	Facilitates autonomous decision making and authorization by participants	Are obligated not to initiate research on a subject without legal authorization

Note. Threshold, informational, and consent elements were adapted from Beauchamp and Childress.[31]

materials that explain the study to participants and can represent the participants' concerns to the researchers. The CAB can act as an advocate for the rights of human subjects, for example, by conveying to participants their right to refuse or their right to full disclosure of information about the benefits and risks of the study and about previous relevant research. Finally, the CAB can provide a set of recommendations to help potential participants decide whether or not to participate in a study.

Practical Examples of CABs in the Research Process

This section highlights some of the ways in which CABs can be implemented in research involving human subjects. These examples come from AIDS research, because the history and experience of using CABs in AIDS-related research have been described previously.[32–40] CAB involvement can, however, be extended to research on other diseases that disproportionately affect communities of color or communities that share a specific identity. These examples also are predominantly from clinical trials research, but CAB involvement can be applied to community-based prevention research (e.g., testing a behavioral intervention) as well.

Formalizing community involvement in research through the use of CABs may greatly improve the informed consent process, study design, and study implementation at different levels of the research. CAB participation has the potential for affecting clinical trials of experimental therapies, particularly those targeting vulnerable populations. Some US federal and state funding agencies have responded to the call for greater community involvement in research by requiring scientists to incorporate CABs into their research protocols, particularly in randomized placebo-controlled clinical trials of experimental therapies and vaccines in HIV/AIDS research.

By 1990, the National Institute of Allergy and Infectious Diseases (NIAID) had formally integrated community representatives into the AIDS Clinical Trials Group (ACTG), the Center for AIDS Research, and the Community Programs for Clinical Research on AIDS to involve community members who had raised concerns about the conduct of AIDS clinical trials.[32] Currently, each of these NIAID-sponsored programs is expected to have a local CAB, with one member of each CAB serving on a national-level advisory board called a Community Constituency Group.

Local CABs can be influential in halting the progress of clinical trials, as shown in the following example. A CAB helped prevent 2 ACTG study protocols from being initiated at the San Francisco, Calif, site, even though both protocols were up and running at the national level. Regarding ACTG 320, which had two arms—AZT/3TC/placebo and AZT/3TC/Crixivan—the San Francisco CAB felt that there were enough data to substantiate the benefits of Crixivan in reducing viral load, and thus having a placebo arm was considered unethical. In ACTG 343, participants were randomized to either a 3-drug, 2-drug, or 1-drug regimen after having been on successful antiretroviral therapy for 6 months. The San Francisco CAB felt that randomizing patients to receive less than the standard of care unnecessarily exposed participants to risk. The study was closed prematurely by an interim review committee, which determined that the risk of virologic rebound was clearly weighted in the 1- and 2-drug arms. This decision convinced the principal investigator not to implement the protocol at the San Francisco site.

The HIV Network for Prevention Trials (HIVNET) was established in 1993 to conduct domestic and international multicenter trials, with a primary focus on conducting phase I and II clinical trials of HIV vaccines.[33] In the following examples, HIVNET CABs played a role in advocating compensation for trial-related injuries and full disclosure of information explaining the benefits and risks associated with trial participation.

• The national HIVNET CAB convinced both NIAID and 2 pharmaceutical sponsors to guarantee compensation for medical costs incurred by participants in the event of physiological harm caused by the candidate preventive HIV vaccine tested that year in a phase II trial.[34] Without CAB input, this issue might have been overlooked by the vaccine trial researchers.

• The national HIVNET CAB was instrumental in creating a participants' bill of rights despite objections from local principal investigators, who believed that the bill of rights simply restated the consent form. The national CAB members thought otherwise, recognizing that individuals need to understand their rights as trial volunteers, given the list of social harms associated with participation, and that such a document would be an important tool for communication in their respective communities.

• The local San Francisco HIVNET CAB wanted to ensure that individuals being enrolled in the commercially sponsored phase III preventive HIV vaccine trial were provided with sufficient information to make a fully educated decision about participation. In particular, CAB members were concerned that potential participants might not fully comprehend the content of the consent forms. Thus, the informed consent process was lengthened into several visits so that these individuals would have time to ask questions and digest the information given to them before making a decision to participate.

The HIV Cost and Services Utilization Study (HCSUS) and the CDC/NIAID-funded Project LinCS (Linking Communities and Scientists) showed that CAB participation has the advantage of forging a true partnership with scientists from the studies' inception.

• HCSUS created a 12-member national CAB that functioned as a conduit for ensuring participation of HIV-seropositive individuals and their advocates in the planning and implementation phases of clinical trial research.[35–36] Among its activities, the HCSUS CAB contributed by identifying research priorities, including a greater emphasis on women-specific issues, and areas of research inquiry that had not been proposed by the researchers before. This CAB was also helpful in the day-to-day operations of the study, for example, by reviewing informed consent forms for content and comprehensibility.

• Project LinCS used CABs to assist in examining community

perceptions about HIV vaccine efficacy trials.[37] Three sites (San Francisco, Calif; Philadelphia, Pa; and Durham, NC) formed and worked with local CABs, and these CABs contributed to different aspects of the research, including problem identification, participant recruitment, research monitoring (including retention and follow-up), and dissemination of study findings.[38] Had CABs not been used, the ability of Project LinCS to recruit study participants, as well as the quality of the interview data collected, would have been greatly affected. Furthermore, 2 resources have been developed with assistance from Project LinCS CABs. First, a video was developed that discusses the 3 communities' perspectives on participating in phase III preventive HIV vaccine trials.[39] Second, the Durham CAB assisted in the development of a brochure that provides a list of questions for potential study participants to ask researchers before deciding whether or not to participate in any given study.[40]

CRITICISMS OF CABS

All research involving human subjects, particularly clinical and behavioral studies, could benefit by having CABs or equivalents to provide advice about informed consent protocols, subject enrollment, research design, and implementation. Yet the use of CABs has not always been seen as conducive to the research process. For example, CABs in clinical trial research are often viewed by researchers as auxiliary, or as "window-dressing."[1] Indeed, it is likely that the dynamic between the principal investigator and the CAB may dictate the extent to which a CAB can influence and guide research. A principal investigator who is willing to listen to the concerns of the CAB and to obtain feedback from its members may be a requirement for an effective CAB.

Second, the resources allocated to the development and management of CABs tend to be limited and are often the first to be cut from study budgets when research priorities are considered. Indeed, in the first phase III trial of a candidate HIV vaccine, the private financial sponsor did not provide funding for CAB development at its 50 North American trial sites, and a national CAB had not been assembled when the study began.[1]

Finally, greater CAB implementation is needed in developing countries, particularly in clinical studies, where there is more at stake in terms of potential risks and social harms. Community involvement sometimes means having trusted local leaders or even family members act as liaisons between scientists and study participants.[2,41–42] This mechanism, however, has its limitations; replacing the autonomy of the individual with the judgment of a community leader or family member may not be in the best interests of prospective research participants. On the other hand, if developing countries could adopt CABs as a component of clinical research, individual informed consent failures, such as confusion over study terminology (e.g., what it means to receive a placebo) and participants' not being fully informed, could be avoided or at least minimized.

CONCLUSION

In most situations, investigators and potential research subjects expect that the decision about research enrollment and the authorization of research will be an individual choice. Yet community perceptions of research and of a specific research project may guide individual action. Having a CAB provides a context for researchers and community members to discuss the intent, risks, benefits, and implications of research projects in culturally sensitive terms.

In spite of the increasing use of CABs, there has been only limited investigation into their impact on the design and implementation of research, particularly AIDS research, where their use is most prevalent. Some attention has been given to examining how CABs can enhance recruitment and participation in AIDS clinical trials.[32] No studies, however, have systematically evaluated the lessons learned from using CABs and their impact on effecting change in the way in which research is conducted. Indeed, one of the criticisms of CAB participation in the research process has to do with not having enough information about the structure of a CAB and how it works to appreciate and evaluate its ability to guide, speak for, and protect its community.[43]

We recognize this as a limitation. We call for a greater effort to devise methods of training investigators in the development and maintenance of CABs and in the selection of community advisors who will see that the interests of the target community, as well as the research priorities of the investigators, are considered.

In a climate where formal research safeguards do not always succeed in protecting the rights of human subjects, the need for community-based methods to augment the process of protection is apparent. CABs reinforce the importance of community involvement in the decision-making process from the inception of a research study, to ensure that consenting human subjects are fully informed about the study in question. We hope that the examples of CAB participation presented here have demonstrated the crucial role communities can play in the ethical conduct of research and how community input may enhance, not detract from, the research process. ■

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This commentary was accepted January 23, 2001.

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R.P. Strauss and S. Sengupta planned and led the writing of this commentary, using the input, ideas, and revisions offered by the other authors. S. Sengupta examined the history of ethical lapses in research. S.C. Quinn and J. Goeppinger reviewed the literature and examined the theoretical aspects of informed consent and participatory research. C. Spaulding, S.M. Kegeles, G. Millett, and R.P. Strauss used their experiences in working with community advisory boards to provide historical and practical examples of how communities have been involved in research.

Acknowledgments

This work was supported in part by UNC-CH, Center for AIDS Research, a program funded by the National Institute of Child Health and Human Development (P30-HD37260); the Centers for Disease Control and Prevention, cooperative agreement U48/CCU409660; and grant T32 MH19105 from the National Institutes of Mental Health.

The authors would like to thank Cathy Emrick, MPH, for her assistance.

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